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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,969	03/30/2006	Takeyuki Sugiura	Q94181	9936
65565	7590	05/01/2007		
SUGHRUE-265550			EXAMINER	
2100 PENNSYLVANIA AVE. NW			CHOWDHURY, IQBAL HOSSAIN	
WASHINGTON, DC 20037-3213				
			ART UNIT	PAPER NUMBER
			1652	
			MAIL DATE	DELIVERY MODE
			05/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/573,969

Applicant(s)

SUGIURA, TAKEYUKI

Examiner

Iqbal H. Chowdhury, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Election/Restrictions

This application is a 371 of PCT/JP04/14812.

Claims 1-20 are currently pending.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-9, 12 and 19, drawn to a DNA molecule of SEQ ID NO: 1 encoding a protein having 10-formyl-tetrahydrofolate synthetase activity, 5,10-methenyl-tetrahydrofolate cyclohydrolase activity, 5,10-methylene-tetrahydrofolate dehydrogenase and 10-formyl-tetrahydrofolate-synthetase activity, transformant and a kit comprising said DNA for diagnosing colon cancer.

II. Claims 10 and 19, drawn to a polypeptide of SEQ ID NO: 2 having 10-formyl-tetrahydrofolate synthetase activity, 5,10-methenyl-tetrahydrofolate cyclohydrolase activity, 5,10-methylene-tetrahydrofolate dehydrogenase and 10-formyl-tetrahydrofolate-synthetase activity.

III. Claim 13 and 19, drawn to an antibody of said protein and kit comprising said antibody.

IV. Claims 14-15, drawn to a method for identifying a compound that inhibit cell growth and enhance the activity of said protein.

V. Claims 16-18, drawn to a method of diagnosing colon cancer by detecting nucleic acid molecule encoding a polypeptide of SEQ ID NO: 1.

VI. Claims 20, drawn to a preventive agent and/or therapeutic agent for colon cancer, which comprises an inhibitor of said protein.

2. The inventions listed as Groups I - VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the DNA of Groups I, polypeptide of Group II, antibody of Groups III, and therapeutic agent of Group VI are each unrelated and chemically distinct entities. The only shared technical feature of these groups is that they all relate to polynucleotide encoding said polypeptide. However, this shared technical feature is not a "special technical feature" as defined by PCT Rule 13.2 as it does not define a contribution over the art. According to the search report, a DNA encoding polypeptide having said activities is known in the art (WO/2002/083873, published on 10/24/2002, see IDS). Thus, a DNA encoding a polypeptide having said functions does not make contribution over the prior art. Therefore, Groups of inventions I-VI lack special technical feature and lack unity of inventions.

3. The antibody of Group III does not share any "special technical feature" with Group I as the polynucleotides of Group I are neither made nor used by the antibody of Groups III.

4. A method of screening candidate therapeutic compound of Group IV does not share any "special technical feature" with Group I as the polynucleotides of Group I are neither made nor used by the method of screening candidate therapeutic compound of Group IV.

5. A method of diagnosing cancer of Group V does not share any "special technical feature" with polypeptide of Group II as the polypeptide of Group II is neither made nor used by the method of diagnosing cancer of Group V.

6. The methods of Groups IV and V do not have unity of invention with each other as each method comprises unrelated steps as use different products and produce different effects.

37 CFR 1.475 does not provide for multiple products and/or methods within a single application. Therefore, inventions of Group I – VI lack unity of invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

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claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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